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September 18, 2002

VIA FEDEX

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Medical Devices; Needle Bearing Devices - Docket Number 01P-0120
RIN 0910-ZA20

Dear Sir or Madam:

Enclosed please find two copies of the comments of the American Clinical Laboratory Association on the Advance Notice of Proposed Rulemaking issued June 20, 2002 regarding needle bearing devices.

If you have any questions or comments, please feel free to contact me.

Sincerely,

Peter M. Kazon

Enclosure

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American
Clinical Laboratory
Association

Comments of the American Clinical Laboratory Association on the Advance Notice of Proposed Rulemaking for Needle-Bearing Devices

[Docket No. 01P-0120]
RIN 0910-ZA20

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the advance notice of proposed rulemaking ("ANPRM") issued June 20, 2002 regarding needle-bearing devices. 67 *Fed. Reg.* 41890. ACLA is an association representing independent clinical laboratories throughout the United States including local, regional and national laboratories. In the United States alone, clinical laboratories perform millions of tests each year for physicians and other health care professionals. Thus, ACLA members will be significantly affected by the decisions regarding additional regulation of needle-bearing devices.

The Food and Drug Administration ("FDA") has issued the ANPRM because it is concerned about the health risks posed by needle stick and other percutaneous injuries, and in response to a joint petition submitted by Public Citizen's Health Research Group ("HRG") and the Service Employees International Union ("SEIU") requesting that FDA take further action in this area. The clinical laboratory industry is very concerned about employee safety; however, we believe that it is premature for the FDA to take additional action to regulate needle-bearing devices. Moreover, we believe that additional FDA action on these issues is unnecessary because the Occupational Safety and Health Administration ("OSHA") is actively pursuing these concerns.

In particular, the HRG/SEIU petition requested that FDA ban:

- IV catheters, blood collection devices (needles and tube holders) and blood collection needle sets ("butterfly syringes" or "winged collection sets") that do not meet criteria specified in FDA's April 16, 1992 safety alert.
- Glass capillary tubes;
- IV infusion equipment that does not use needleless technology or recessed needles.

Federal law gives FDA the authority to ban a device if it finds that the device presents a "substantial deception or an unreasonable and substantial risk of illness or injury." *See* 21 U.S.C. § 360f. The pertinent federal regulations state that, in determining whether the risk of illness is substantial, FDA must consider whether the risk posed by continuing marketing of the device is important, material, or significant in relation to the benefit to the public health from continued marketing. *See* 21 C.F.R. § 895.21(a)(1).

These devices should not be banned because there are legitimate uses for them.

The clinical laboratory industry is concerned about the safety of its health care workers, and commends the FDA for its efforts to address these concerns. However, ACLA does not

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believe that these devices should be banned. The devices do not present a "substantial deception or an unreasonable and substantial risk of illness or injury" because the risks posed by the devices are not significant in relation to the benefit to the public health from their continued use.

The health care environment is more complicated than the ANPRM acknowledges. In particular, the ANPRM discounts the vast uses and needs for medical devices such as conventional needles. ACLA members are committed to providing employees with necessary training and making available safer blood drawing devices. Ultimately, however, medical professionals must choose the devices they are most comfortable with and that are the most appropriate for the medical indications in the particular situation and the needs of patients. Because there are applications that remain for the use of these medical devices, depending on the situation, ACLA believes that they should not be arbitrarily or comprehensively banned.

Further, some blood collection devices (needles) can be retrofitted with safety devices to conform to OSHA requirements (summarized below). Thus, as long as device manufacturers continue to develop ways to retrofit and upgrade devices, it would be difficult for FDA to determine whether any product would pose any unacceptable risk of illness or injury.

Training of health care professionals is the most effective method for reducing needle stick injuries.

Independent clinical laboratories employ thousands of phlebotomists and nurses to perform blood drawing services. These highly trained health care professionals perform millions of blood draws each year and in the course of doing so may use these devices in a variety of different situations. Although the clinical laboratory industry has actively moved towards the use of safety devices, phlebotomists and nurses are required to make professional judgments about the proper device for a given situation. In order to provide appropriate and high-quality health care services to patients, health care personnel must be given this discretion to choose appropriate means for rendering health care services.

Furthermore, although clinical laboratories are moving toward using the safest needles commercially available, there are still medical indications for devices such as butterfly needles. The choice of device depends on a variety of factors, including the professional's preference and general practices, the patient's comfort, and the medical application. Medical professionals ultimately do what they think is best. Thus, employee training, and not necessarily further device regulation, is still the best method for preventing exposure.

Ensuring that health care workers are properly trained is a task over which OSHA has jurisdiction in relation to the bloodborne pathogens standard. The OSHA bloodborne pathogens standard requires employers to develop and implement detailed plans for employee information and training, including warnings through labels, signs, and training to eliminate or minimize their exposure to bloodborne pathogens. The mandated training must include making accessible a copy of the regulatory text of the standard and explanation of its contents, general discussion on bloodborne diseases and their transmission, exposure control plan, engineering and work practice controls, personal protective equipment, hepatitis B vaccine, response to emergencies involving blood, how to handle exposure incidents, the post-exposure evaluation and follow-up program,

and signs/labels/color-coding. The training must also include an opportunity for questions and answers, and the trainer must be knowledgeable in the subject matter. Laboratory workers in particular must receive additional specialized training. Clinical laboratories also provide phlebotomists with extensive usage training on the selected safety devices.

Recently, OSHA also issued a compliance directive containing additional guidance on implementing the bloodborne pathogen standard. This directive focuses on the requirement that employers select safer needle devices as they become available and involve employees in identifying and choosing those devices. The directive reminds OSHA compliance offers that no one safer medical device is appropriate for all situations and suggests that employers consider and implement devices that are appropriate, commercially available and effective.

Thus, reducing the risk of needle stick injuries is not simply about regulation of the needle-bearing device itself. In order to be effective, regulation must focus more on training and education of personnel. Moreover, health care professionals must be afforded significant discretion to determine what is appropriate for a particular patient in a given situation.

Most needle stick injuries do not occur as part of the blood drawing process.

ACLA believes that the ANPRM takes an overly broad approach to addressing the perceived problem. The data referenced in the ANPRM seems to suggest that needle stick injuries that occur as part of the blood drawing process are a very small part of the overall sharps injuries that occur. In fact, most of the injuries are from hypodermic needles, which are unlikely to be used in a standard blood draw for collecting a specimen for laboratory testing. The data presented in the ANPRM also appears to be based on the experience of hospitals, which represent a substantially different environment and experience than clinical laboratories in terms of setting, types of blood draws, and patients.

The risk of a possible needle stick injury can never be completely eliminated, even when safety needles are consistently used. ACLA members' experience is that the majority of needle stick injuries in this setting occur before the safety device is fully engaged (*e.g.*, as a result of a combative patient or during the time period between removing the needle and activating the safety device). Since blood drawing devices are not a major part of the problem, ACLA believes that it would be unreasonable and inappropriate to ban these types of devices. Instead, regulatory action should focus more closely on where and how the majority of needle stick injuries occur and specifically address these situations in order to protect health care workers.

There is not sufficient data yet to develop a performance standard.

Although the clinical laboratory industry is strongly committed to protecting its employees, ACLA feels that there is no justification for banning these devices, based on current use and current statistics. Certainly, there may be instances where these devices are the most appropriate device for providing the particular health care service. With regard to a performance standard, the clinical laboratory industry has not yet reached a point where it could develop meaningful criteria because it is still at the beginning of the process of determining what safety devices are effective and useful.

Nonetheless, any type of performance standard must be based on a number of factors, including the incremental increase in safety, the costs of implementing the standard, and the impact on patient care. It is important to consider that the current "first-generation" safety needle products are limited in their ability to reduce needle sticks because they are not automatic. Because the safety feature is not automatically engaged on the device, there is always a window of exposure. Training is the key to reducing the risks of exposure, but given the inherent limitations in the product, the problem cannot be completely eliminated. In addition, moving from conventional needles to the first generation of safety needles has increased laboratories' costs by as much as 140 %. It is unclear what the financial impact of moving to the next generation of safety devices will be. Further, these factors must be evaluated in the context of the Medicare payment system, which has been paying the same amount for blood draws since 1984 – $3.

ACLA would be interested in working with OSHA and FDA to develop a voluntary standard.

ACLA members would be interested in working with both OSHA and FDA to develop a voluntary standard for the safe use of blood collection devices. ACLA believes that the exposure control plan required by the OSHA bloodborne pathogen standard is fairly comprehensive and its approach to needle sticks is intended to take into account a variety of factors, not simply the actual needle-bearing device. This approach could be useful as a first step in creating a standard for using safety needle devices.

We hope you find these comments useful and we look forward to working with OSHA and FDA to ensure that employees are appropriately protected from needle stick injuries and patients have access to important, high-quality health care services.

WDC 319810v1

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